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Medication Assisted Treatment Protocol

EXHIBIT

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1. PURPOSE

This policy is intended to ensure that patients who have Opioid Use Disorder (OUD), and are willing to receive Medication Assisted Treatment (MAT), do so based on feasibility per facility rules and Practitioner's waiver to prescribe. This policy also addresses those with Alcohol Use Disorder (AUD) who are willing to receive MAT (naltrexone) for that diagnosis.

Practitioners shall be notified of pregnant patients who have a history of active opiate use upon identification, such that significant withdrawal does not take place. Pregnancy requires continued opioid substitution to prevent withdrawal complications for the fetus.

2. SCOPE

This policy applies to health care staff.

3. POLICY

Upon admission, patients shall be screened by the Registered Nurse or Practitioner for OUD. Patients, who are willing and are appropriate candidates in facilities wherein buprenorphine is allowed, and Practitioners who have special dispensation from the Drug Enforcement Agency in the form of a DEAx waiver to prescribe, may be offered continuation or induction of MAT while incarcerated. Options other than buprenorphine shall be presented to the patient where available. These other options include methadone, naltrexone and abstinence. Likewise, patients who enter correctional facilities on MAT shall have these medications continued as clinically indicated.

4. INTERPRETATION

This policy is to be interpreted by the Wellpath Chief Clinical Officer or designee.

5. PROCEDURE

- 5.1. For patients who are receiving buprenorphine in the community, who enter facilities where buprenorphine is allowed, and the Practitioners have DEAx waivers to prescribe:
 - 5.1.1. Attempts shall be made to verify buprenorphine use (and if possible patient compliance) per policy OPS-300_E-09A Medication Verification. However, the Practitioner shall be contacted prior to the time of the next dose, based on patient history.
 - 5.1.2. The Practitioner (or the Practitioner's designee if allowable) shall search for the patient in a Prescription Drug Monitoring Program.
 - 5.1.3. A urine drug screen and urine pregnancy test (as applicable) shall be done prior to the first dose of buprenorphine. If the urine drug screen is positive for

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a drug other than buprenorphine, the case shall be discussed with the Facility Medical Director. The patient's community provider may also be contacted to gather additional history. The Facility Medical Director shall be contacted in regards to any inmate that tests positive for pregnancy and reports active substance use or whose urine tests positive for a drug.

- 5.1.4. This medication shall be ordered by the Practitioner at a clinically appropriate dose (see ATTACHMENT 1).
- 5.1.5. The patient's personal supply of buprenorphine shall not be used.
- 5.1.6. In the event that the MAT cannot be verified in a timely manner, the decision to continue MAT shall be made by the Practitioner on a case by case basis.
- 5.2. For patients receiving methadone as MAT in the community, and enter facilities where the facility does not have an Opioid Treatment Program (OTP):
 - 5.2.1. Attempts shall be made to verify methadone use (and if possible patient compliance) per policy OPS-300_E-09A Medication Verification. However, the Practitioner shall be contacted prior to the time of the next dose, based on patient history.
 - 5.2.2. The Practitioner (or the Practitioner's designee if allowable) shall search for the patient in a Prescription Drug Monitoring Program.
 - 5.2.3. A urine drug screen and urine pregnancy test (as applicable) shall be done prior to the first dose of methadone. If the urine drug screen is positive for a drug other than methadone, the case shall be discussed with the Facility Medical Director. The patient's community provider may also be contacted to gather additional clinical history. The Facility Medical Director shall be contacted in regards to any inmate that tests positive for pregnancy and reports active substance use or whose urine tests positive for a drug.
 - 5.2.4. Upon verification of this medication, the site Practitioner can order the methadone at a fixed, once-daily dose for no more than 3 days. The Practitioner shall discuss available treatment options with the patient including medically supervised withdrawal, abstinence, and other clinically appropriate MAT.
 - 5.2.5. The patient's personal supply of methadone shall not be used.
 - 5.2.6. In the event that the MAT cannot be verified in a timely manner, the decision to continue MAT shall be made by the Practitioner on a case by case basis.
- 5.3. For patients receiving methadone as MAT in the community and enter facilities where the facility is an Opioid Treatment Program (OTP):

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5.3.1. Attempts shall be made to verify methadone use (and if possible patient compliance) per policy OPS-300_E-09A Medication Verification. However, the Practitioner shall be contacted prior to the time of the next dose, based on patient history.

- 5.3.2. The Practitioner (or the Practitioner's designee if allowable) shall search for the patient in a Prescription Drug Monitoring Program.
- 5.3.3. A urine drug screen and urine pregnancy test (as applicable) shall be done prior to the first dose of methadone. If the urine drug screen is positive for a drug other than methadone, the case shall be discussed with the Facility Medical Director. The patient's community provider may also be contacted to gather additional clinical history. The Facility Medical Director shall be contacted in regards to any inmate that tests positive for pregnancy and reports active substance use or whose urine tests positive for a drug.
- 5.3.4. Upon verification of this medication, the Practitioner shall order the methadone per the procedure in the OTP policy.
- 5.3.5. The patient's personal supply of methadone shall not be used.
- 5.3.6. In the event that the MAT cannot be verified in a timely manner, the decision to continue MAT shall be made by the Practitioner on a case by case basis.
- 5.4. For patients who are receiving naltrexone in the community, and enter facilities where naltrexone is allowed:
 - 5.4.1. Attempts shall be made to verify naltrexone use (and if possible patient compliance) per policy OPS-300_E-09A Medication Verification. However, the Practitioner shall be contacted prior to the time of the next dose, based on patient history.
 - 5.4.2. The Practitioner (or the Practitioner's designee if allowable) shall search for the patient in a Prescription Drug Monitoring Program.
 - 5.4.3. A urine drug screen and urine pregnancy test (as applicable) shall be done prior to the first dose of naltrexone. If the urine drug screen is positive for a drug of abuse, the case shall be discussed with the Facility Medical Director. The patient's community provider may also be contacted to gather additional history. The Facility Medical Director shall be contacted in regards to any inmate that tests positive for pregnancy and reports active substance use or whose urine tests positive for a drug.
 - 5.4.4. Upon verification of this medication, the Practitioner shall be contacted. If the patient is verifiably on injectable naltrexone for extended-release (Vivitrol), no intervention is necessary until 7 days prior to the date of the next injection. At that point, oral naltrexone shall be started and continued throughout the

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incarceration. If the patient enters the facility verifiably on oral naltrexone, the Practitioner shall order that it be continued.

- 5.4.5. The patient's personal supply of naltrexone shall not be used.
- 5.4.6. In the event that the MAT cannot be verified in a timely manner, the decision to continue MAT shall be made by the Practitioner on a case by case basis.
- 5.5. For potential OUD patients NOT receiving MAT in the community, who enter facilities where buprenorphine, methadone, and/or naltrexone is permitted by facility, with a Practitioners with DEAx waivers to prescribe (buprenorphine only):
 - 5.5.1. Withdrawal from substance of abuse shall occur per policy OPS-300_F-04 Medically Supervised Withdrawal and Treatment, except in the case of pregnant patients.
 - 5.5.2. Beginning the day after withdrawal has been completed, nursing staff shall conduct daily wellness checks for 3 days. Patients who answer affirmatively to any of the wellness questions shall be placed on mental health watch and referred to the mental health professional (if watch initiated by nursing) or psychiatric Practitioner.
 - 5.5.3. Upon admission, the nurse shall screen for interest in MAT using the DAST 10 tool. Patients with a negative DAST 10 shall be educated on drug abuse and given information regarding resources in the community, asked to sign an agreement for abstinence. Patients with a positive DAST 10, shall have a DSM 5 OUD screening interview no later than the patient's initial mental health appraisal.
 - 5.5.4. The qualified mental health professional conducting the DSM 5 OUD screening interview shall review the latest Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for OUD. Patients with ≤ 1 criterion shall be educated on drug abuse and given information regarding resources available while in custody and in the community, asked to sign an agreement for abstinence. Patients with ≥ 2 criteria shall be referred to a qualified mental health professional to confirm the diagnosis.
 - 5.5.5. Upon evaluation by the qualified mental health professional, the diagnosis of OUD shall be assessed. If this diagnosis is not supported, then the patient shall be educated on drug abuse and given information regarding resources available while in custody and in the community. If the diagnosis is confirmed, then the patient shall be referred to the DEAx waivered Practitioner to discuss treatment options.
 - 5.5.6. The DEAx waivered Practitioner shall discuss available treatment with the patient. Treatment options include abstinence, naltrexone, methadone (in

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conjunction with OTP), and buprenorphine. Those patients who are prescribed MAT shall be referred for follow-up through chronic care clinic.

- 5.5.7. Patients who choose <u>abstinence</u> shall be provided with a list of resources available while in custody and community resources that are available to them upon release. An agreement for abstinence shall be obtained. The use of the sick call process shall be encouraged should the patient reconsider MAT. Upon reconsideration of MAT in a patient who initially declined, MAT initiation shall not occur with less than 7 days left on the patient's sentence. In cases when it is not clinically appropriate to initiate MAT due to proximity to release, patients shall be referred to community resources as part of their reentry plan. Substance abuse counselling shall be offered on an on-going basis.
- 5.5.8. Patients who choose <u>methadone</u> shall be referred to the OTP for management. If an OTP is not available, then this shall not be considered as a viable alternative for MAT. Patients shall be seen in chronic care clinic every 30 days until the patient's dosing is stabilized. Lab studies shall be performed as clinically indicated. The patient shall be seen in chronic care clinic every 6 months thereafter or as otherwise clinically indicated. CBC and Complete Metabolic Profile shall be obtained no less than annually. EKG shall be considered as clinically indicated. Records from the OTP shall be reviewed at each chronic care clinic visit. Substance abuse counselling shall be offered on an on-going basis. For sites that are accredited OTPs, please refer to the local policy manual for information on that program.

5.5.9. **Naltrexone** shall be managed as follows:

- 5.5.9.1. Screening labs (CBC & Complete Metabolic Panel, Urine Drug Screen, Urine Pregnancy Test (as applicable)) shall be done at the first chronic care visit.
- 5.5.9.2. Patient shall be seen back in chronic care clinic to review labs. If no contraindications are noted in the lab work, a consent for naltrexone and a treatment agreement shall be signed by the patient.
- 5.5.9.2.1. If initiation of naltrexone is clinically contraindicated due to lab results, formulate a treatment plan that addresses abnormal lab values with appropriate F/U schedule. Discuss available MAT options again with patient in light of abnormal lab values.
- 5.5.9.3. Oral naltrexone shall be started during this follow-up visit. This medication can be given in the housing units during regular medication pass.

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- 5.5.9.4. Patients shall be seen in chronic care clinic every 30 days until the patient's dosing is stabilized. The patient shall be seen in chronic care clinic every 6 months thereafter or as otherwise clinically indicated. Lab studies shall be performed as clinically indicated. CBC and Complete Metabolic Profile shall be obtained no less than annually.
- 5.5.9.5. Substance abuse counselling/Mental Health follow-up shall be offered on an ongoing basis as available.
- 5.5.9.6. Referral to discharge planning shall be done.
- 5.5.9.7. The patient's treatment plan shall include transition to injectable naltrexone for extended-release (Vivitrol) prior to the patient's anticipated release date. The Practitioner shall determine the number of doses to be administered prior to the patient's anticipated release date. Timing of administration shall be such that the patient receives an injection of naltrexone for extended-release one week prior to the anticipated release date. Oral naltrexone shall be discontinued. If patients opt to continue with oral naltrexone after release, they shall be educated on the sub-optimal clinical results of this treatment modality in the community setting. Should they still opt to continue the oral formulation, the naltrexone injection shall not be given. The oral naltrexone shall be continued and appropriate follow-up made for after release.
- 5.5.9.8. A follow-up appointment for additional naltrexone injections in the community shall be provided to the patient when reviewing the discharge plan.
- 5.5.9.9. Please note that naltrexone can also be used for the treatment of alcohol dependency. Should a patient meet the criteria for this diagnosis, then the above naltrexone procedure would be applicable to them as well.

5.5.10. **Buprenorphine** shall be managed as follows:

- 5.5.10.1. Screening labs (CBC & Complete Metabolic Panel, Urine Drug Screen, Urine Pregnancy Test (as applicable) shall be done at the first chronic care visit.
- 5.5.10.2. Patient shall be seen back in chronic care clinic to review labs. If no contraindications are noted in the lab work, a consent for buprenorphine and a treatment agreement shall be signed by the patient.
- 5.5.10.2.1. If initiation of buprenorphine is contraindicated due to lab results, formulate a treatment plan that addresses abnormal lab values with appropriate F/U schedule. Discuss available MAT options again with patient in light of abnormal lab values.
- 5.5.10.3. Induction onto buprenorphine shall be offered as seen in ATTACHMENT 1.

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- 5.5.10.4. Patients shall be seen in chronic care clinic every 30 days until the patient's dosing is stabilized. The patient shall be seen in chronic care clinic every 6 months thereafter or as otherwise clinically indicated. Lab studies shall be performed as clinically indicated. CBC and Complete Metabolic Profile shall be obtained no less than annually. Substance abuse counselling/Mental Health follow-up shall be offered on an on-going basis as available.
- 5.5.10.5. Discharge planning shall be done to ensure that the patient has an appointment with their community MAT Practitioner as well as a sufficient supply of medication upon release.
- 5.6. Patients receiving MAT in the community, who enter facilities where the Practitioners do NOT have DEAx waivers to prescribe:
 - 5.6.1. Buprenorphine use shall be verified per policy (and if possible, patient compliance) OPS-300_E-09A Medication Verification.
 - 5.6.2. The Practitioner (or their designee if allowed) shall search for the patient in a Prescription Drug Monitoring Program.
 - 5.6.3. Patients shall be referred to a DEAx waived Practitioner as soon as possible to continue this medication. These patients shall also receive counseling either on or off-site as appropriate.

6. DEFINITIONS

Addictionologist: Licensed Medical Doctor experienced in the specialty field of Addiction Medicine. Addictionologist provides clinical support to Practitioners, and direct or consultative care to inmate patients.

Facility Medical Director: Licensed Medical Doctor who has administrative and clinical oversight at each facility in the Massachusetts Department of Correction. Facility Medical Directors are employed solely by Wellpath.

Opioid Use Disorder: A diagnosis requiring a pattern of using opioids causing clinically significant impairment or distress that meets at least 2 of the following criteria:

- 1. Taking the opioid in larger amounts and for longer than intended
- 2. Wanting to cut down or quit but not being able to do it
- 3. Spending a lot of time obtaining the opioid
- 4. Craving or a strong desire to use opioids
- 5. Repeatedly being unable to carry out major obligations at work, school, or home due to opioid use
- 6. Continuing use despite persistent or recurring social or interpersonal problems caused or made worse by opioid use
- 7. Stopping or reducing important social, occupational, or recreational activities due to opioid use

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- 8. Recurrently using opioids in physically hazardous situations
- 9. Consistently using opioids despite acknowledgment of persistent or recurrent physical or psychological difficulties from using opioids
- 10.*Being tolerant for opioids as defined by either a need for markedly increased amounts to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount
- 11.*Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal
- *This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Practioner: Licensed Nurse Practitioner, Physician Assistant, Medical Doctor or Doctor of Osteopathic Medicine providing direct care to patients at all of the Massachusetts Department of Correction facilities. Practitioners are employed solely by Wellpath.

REFERENCES

- American Society of Addiction Medicine (ASAM). The ASAM National Practice Guideline
 For the Use of Medications in the Treatment of Addiction Involving Opioid Use. American
 Society of Addiction Medicine. June 1, 2015
- Substance Abuse and Mental Health Services Administration (SAMHSA). Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Rockville, MD: Center For Substance Abuse Treatment. Treatment Improvement Protocol Series, No. 40, USDHHS Publication (SMA) 04-3939. 2004b
- Substance Abuse and Mental Health Services Administration (SAMHSA). Use of Buprenorphine in the Pharmacologic Management of Opioid Dependence: A Curriculum for Physicians. Substance Abuse and Mental Health Services Administration. 2001

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ATTACHMENT 1

Clinical Guidance for Induction, Stabilization, and Maintenance on Buprenorphine

Obtain urine drug screen prior to induction.

Day 1-7

Buprenorphine 4mg SL QDay x 7 days.

Craving assessments shall be done daily during this time. If cravings are high, then additional dose may be indicated.

On Day 7, if the patient reports no cravings, then buprenorphine 4mg SL shall be continued and the patient shall follow-up in chronic care clinic every 30 days until dosing is stabilized. The patient shall be seen in chronic care clinic every 6 months thereafter or as otherwise clinically indicated

If the patient is still experiencing cravings, then proceed to Day 8-14 guidance.

Day 8-14

Buprenorphine 8mg SL QDav x 7 days.

Craving assessments shall be done daily during this time. If cravings are high, then additional dose may be indicated.

On Day 14, if the patient reports no cravings, then buprenorphine 8mg SL shall be continued and the patient shall follow-up in chronic care clinic every 30 days unit dosing is stabilized. The patient shall be seen in chronic care clinic every 6 months thereafter or as otherwise clinically indicated.

If the patient is still experiencing cravings, then the DEAx waivered Facility Medical Director shall be consulted for guidance.

Obtain random urine drug screen as clinically indicated by Practitioner but no less often as every 6 months.